

PATENT COOPERATION TREATY

CONFIRMATION

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

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1 1 MAY 2005

RECEIVED

PCT

WRITTEN OPINION OF THE INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

(PCT Rule 66)

Date of mailing
(day/month/year)

0 5 MAY 2005

Applicant's or agent's file reference
FP2262

REPLY DUE

within **TWO MONTHS**
from the above date of mailing

International application No.
PCT/SG2004/000168

International filing date (day/month/year)
4 June 2004

Priority date (day/month/year)
5 June 2003

International Patent Classification (IPC) or both national classification and IPC

Int. Cl. ⁷ C12N 15/12, 15/63, C07K 7/00, 14/463, A61K 38/00, A61P 7/02, 9/10

Applicant

NATIONAL UNIVERSITY OF SINGAPORE et al

1. ☒ The written opinion established by the International Searching Authority:
☒ is ☐ is not
considered to be a written opinion of the International Preliminary Examining Authority.

2. This **second** (second, etc.) opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

3. The applicant is hereby invited to reply to this opinion.

- When?** See the Reply Due date indicated above. However, the Australian Patent Office will not establish the Report before the earlier of (i) a response being filed, or (ii) one month before the Final Date by which the international preliminary examination report must be established. The Report will take into account any response (including amendments) filed before the Report is established. If no response is filed by 1 month before the Final Date, the international preliminary examination report will be established on the basis of this opinion. Applicants wishing to have the benefit of a further opinion (if needed) before the report is established should ensure that a response is filed at least 3 months before the Final Date by which the international preliminary examination report must be established.
- How?** By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.
- Also** For an additional opportunity to submit amendments, see Rule 66.4. For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4bis. For an informal communication with the examiner, see Rule 66.6.

4. The FINAL DATE by which the international preliminary report on patentability (Chapter II of the PCT) must be established according to Rule 69.2 is: 5 October 2005

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WRITTEN OPINION OF THE
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

International application No.

PCT/SG2004/000168

Box No. I Basis of the opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

- ☐ This opinion is based on a translation from the original language into the following language which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1 (b))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this opinion has been established on the basis of *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed.")*:

- ☒ the international application as originally filed/furnished
- ☐ the description: pages , as originally filed/furnished
pages , received by this Authority on with the letter of
pages , received by this Authority on with the letter of
- ☐ the claims: pages , as originally filed/furnished
pages , as amended (together with any statement) under Article 19,
pages , received by this Authority on with the letter of
pages , received by this Authority on with the letter of
- ☐ the drawings: pages , as originally filed/furnished
pages , received by this Authority on with the letter of
pages , received by this Authority on with the letter of
- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to the sequence listing (*specify*):

4. ☐ This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to the sequence listing (*specify*):

WRITTEN OPINION OF THE
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

International application No.

PCT/SG2004/000168

Box No. V Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 1-40	YES
	Claims	NO
Inventive step (IS)	Claims 1-23, 25, 29, 30, 37, 38	YES
	Claims 24, 26-28, 31-36, 39, 40	NO
Industrial applicability (IA)	Claims 1-40	YES
	Claims	NO

2. Citations and explanations:

The following documents, first raised in the corresponding International Search Report, are referred to as follows:

D1 – Indian Heart Journal, 1986, Vol. 38, No. 5, pages 369-372

D2 – Comparative Biochemistry and Physiology, Part B: Biochemistry & Molecular Biology (2002), 131B(4), pages 749-756

D3 – EP 671 171

D1 concerns the reduction of cholesterol in acute myocarditis produced by scorpion (*Buthus tamulus*) venom injection. Claims 1-23 and 25-40 concern reductase inhibiting peptides from the scorpion *Buthus martensii* Karsch. These peptides are not obvious from the above mentioned document. Claim 24 concerns isolated peptides which have the function of HMGCoA reductase inhibitor e.g. for reducing accumulation of cholesterol. From the molecular weights of the peptides it seems clear that unity is given because these are the molecular weights of the peptides from a scorpion (see claims 22 and 25). However, a person skilled in the art knows that usually enzymes or peptides with enzyme function are involved in biological processes and he knows from D1 that scorpion venom compounds reduce cholesterol in mammals. Thus the person skilled in the art will try to find similar compounds in other scorpions. Therefore, the subject matter of claim 24 is obvious. In so far as the claims 26-28, 31-36, 39 and 40 are dependent from claim 24 they are also obvious.

D2 deals with peptides from the scorpion *Buthus martensii* Karsch. But this document does not concern cholesterol and diseases caused by cholesterol such as arteriosclerosis or stroke.

D3 relates to HMG CoA reductase inhibitors for the treatment of cardiovascular events. Venoms from scorpions are not mentioned therein.

Accordingly novelty is recognised for the subject matter of all claims. Claims 1-23, 25, 29, 30, 37 and 38 comply with the requirements of inventive step; claims 24, 26-28, 31-36, 39 and 40 do not.

Industrial applicability is acknowledged.